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10/626,275	07/24/2003	Ernest J. Lee	PC28017	9606

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PFIZER INC
Mary J Hosley
150 EAST 42ND STREET
MS: 150/02/E112
NEW YORK, NY 10017-5612

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSNY@Pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/626,275	LEE ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12-21 and 23-27* is/are pending in the application.

4a) Of the above claim(s) *26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-10,12-21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/5/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2009 has been entered.

Status of Claims

Claims 1, 3-10, 12-21 and 23-27 are pending in the present application. Claims 26-27 remain withdrawn from further consideration as being directed to non-elected subject matter. Thus, claims 1, 3-10, 12-21 and 23-25 are examined herein on the merits for patentability. No claim is allowed at this time.

Terminal Disclaimer

The terminal disclaimer filed on 21 August 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on US Application Number 10/626,166 has been reviewed and is NOT accepted. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because: The person who signed the terminal disclaimer is not recognized as an

officer of the assignee, and he/she has not been established as being authorized to act on behalf of the assignee. See MPEP § 324. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

It is noted that applicants filed a Statement under 37 CFR 3.73(b) on 14 October 2009 requesting entry of the terminal disclaimer. However, at the time the TD was filed it was defective. Therefore, filing a proper terminal disclaimer is required in order to obviate the double patenting rejection presented herein below.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 05 October 2009 is being considered by the examiner.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Objections

1. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Claim 21 recites that the pramipexole is in the form of "one to a small plurality of dosage units" administered at the same time. However, claim 21 is dependent from claim 1 which recites that the pramipexole composition is in the form of "a full daily dose contained in a single dosage unit". Thus, "a small plurality of dosage units" fails to further limit "a single dosage unit".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1, 3-10, 12-21 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite "no more than about", "greater than about", "at least about", "not greater than about", "about 0.1 to about 10", "about 0.2 to about 6", and "about 0.3 to about 5". A range, such as greater than, less than, between, etc., implies that the recited value is above a distinct value, below distinct value, or between two distinct end point values. The term "about" implies that values other than the recited value are encompassed within the range. Therefore, it is unclear where the range begins and ends and what values are

encompassed by the range when the range includes the term “about”. It is recommended that applicants delete the term “about” from the ranges in order to clarify the distinct end point values of each range.

2. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 15 recites, "a fluctuation ratio that is not substantially greater than that of an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation, administered three times daily.” However, applicants have not defined the reference formulation. Therefore, it is not clear what formulation is being used to determine the fluctuation ratio. Also, "not substantially greater" is indefinite because it is not clear what is intended by “substantially greater”. The term "substantially greater" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-10, 12-21 and 23-25 are rejected under 35 U.S.C. 102(a) and 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Holman (US 6,277,875) in view of Pospisilik '240 (US 2002/0103240) and Vandecruys et al. (WO 00/59477) (cited in the IDS filed 29 April 2004).

Holman discloses a composition comprising ***pramipexole dihydrochloride monohydrate*** as the active ingredient and as inactive ingredients lactose hydrous, ***pregelatinized starch***, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, purified water, carnauba wax, ***hydroxypropyl methylcellulose***, titanium dioxide, polyethylene glycol, synthetic iron oxide, and polysorbate 80 (col. 11, ln. 35-46). Homan discloses treating patients with pramipexole at a dose of 0.125 mg once per day at bedtime (qhs) followed by gradually increasing the active on a weekly basis until the patient exhibits a therapeutic effect or intolerance (col. 9, ln. 59 to col. 10, ln. 4). Holman discloses administering pramipexole at up to 6.0 mg qhs (Table 1), wherein the effective dose of pramipexole is usually between about 0.125 mg qhs to about 15.0 mg qhs, more usually between about 0.25 mg qhs and about 6.0 mg qhs (col. 10, ln. 5-36).

With respect to the *in vitro* release profile and the *in vivo* absorption profile, the examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347,

51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." The pramipexole-containing compositions according to Holman comprise the same components as instantly claimed (pramipexole, HPMC and pregelatinized starch), and are administered once daily at bedtime (qhs). Thus, the compositions according to Holman inherently possess sustained release profile according to the instant invention in order to be administered in the same amount with the same dosing schedule.

In the event the compositions according to Holman do not inherently possess the *in vitro* release profile and the *in vivo* absorption profile as instantly claimed, Pospisilik '240 teaches controlled release pellet or tablet compositions may be produced using pramipexole ([0064]). Vandecruys et al. teach controlled release compositions comprising an active ingredient (i.e., anti-Parkinsonian drugs), pregelatinized starch and a hydrophilic polymer, wherein the combination of pregelatinized starch and hydrophilic polymer affords controlled release that is safeguarded or maintained in release media of changing ionic strength, i.e. along the entire gastrointestinal tract both in fasted as well as in fed conditions (Abstract; pg. 4, ln. 32 to pg. 5, ln. 3; and pg. 8, ln. 9). Vandecruys et al. further teach an example wherein the controlled release composition resulted in

11.99% release of the active ingredient at 1 hr, 17.74% release at 2 hr, 25.8% release at 4 hr and 33.26% release at 6 hr (Table 5).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art to formulate pramipexole as a controlled release formulation wherein the drug is administered once daily and exhibits the *in vitro* release profile and the *in vivo* absorption profile as instantly claimed.

Response to Arguments

It is noted that Applicants argued on 07 December 2007 that Holman teaches administering MIRAPEX®, which is an immediate release formulation of pramipexole that requires administering three times per day. Applicants submitted a Physician's Desk Reference (PDR) teaching MIRAPEX® wherein the pramipexole is rapidly absorbed and reaches peak plasma concentrations in approximately 2 hours. However, after further inspection, the examiner respectfully notes that the inactive ingredients for the pramipexole compositions according to Holman and the PDR presented by applicants are not the same. Holman discloses the compositions comprising pregelatinized starch, HPMC and other excipients whereas the PDR does not include these components. Therefore, it is not clear that the compositions comprising pramipexole according to Holman will have the same pharmacokinetic profile as the composition according to the PDR. Furthermore, Holman clearly teaches that the preferred dosing of the pramipexole according to their invention is 0.25 to 6.0 mg qhs, as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 3-10, 12-21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pospisilik '240 (US 2002/0103240) in view of Vandecruys et al. (WO 00/59477).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Pospisilik '240 teaches controlled release pellet or tablet compositions may be produced using pramipexole comprising a mixture of pramipexole salt, a suitable filler, such as microcrystalline cellulose, and a suitable release controlling agent comprising water and/or a water-insoluble macromolecular substance such as an acrylate polymer or a modified cellulose ([0064]). Pospisilik '240 further teaches that pramipexole is commercially available as the dihydrochloride salt ([0004]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Pospisilik '240 does not teach the controlled release of pramipexole to comprise a starch and a hydrophilic polymer and have an *in vitro* release profile wherein at 2 hours no more than 20% pramipexole has dissolved, or an *in vivo* absorption profile wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours, as instantly claimed. Pospisilik '240 also does not teach the controlled release pramipexole wherein the pramipexole is in the form of a dosage unit that is given as a daily dose in one dosage unit, as instantly claimed.

However, Vandecruys et al. teach controlled release compositions comprising an active ingredient (i.e., anti-Parkinsonian drugs), pregelatinized starch and a hydrophilic polymer, wherein the combination of pregelatinized starch and hydrophilic polymer affords controlled release that is safeguarded or maintained in release media of changing ionic strength, i.e. along the entire gastrointestinal tract both in fasted as well as in fed conditions (Abstract; pg. 4, ln. 32 to pg. 5, ln. 3; and pg. 8, ln. 9). Vandecruys et al. further teach an example wherein the controlled release composition resulted in 11.99% release of the active ingredient at 1 hr, 17.74% release at 2 hr, 25.8% release at 4 hr and 33.26% release at 6 hr (Table 5).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to prepare controlled release pramipexole dihydrochloride salt compositions, as taught by Pospisilik '240, wherein the controlled release compositions comprise pregelatinized starch and a hydrophilic polymer and are suitable for once daily administration, as reasonably taught by Vandecruys et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue that Ju (US 6,197,339) teaches twice daily administration and does not teach that the composition can be modified to obtain once daily administration. Thus, the rejections over Ju are withdrawn. However, Vandecruys et al. teach that controlled release of active ingredients allows simplifying the patient's posological scheme by reducing the amount of recommended daily intakes and improves patient's compliance. One should not underestimate the positive psychological effect towards the patient of a once daily intake instead of a twice or multiple daily intake (pg. 2, ln. 18-26). Therefore, Vandecruys et al. clearly provide motivation for formulating controlled release of active ingredients wherein the preparation is administered once daily. Furthermore, Vandecruys et al. teach that hydrophilic polymers in combination with pregelatinized starch affords controlled release of active ingredients that can be

safeguarded and maintained in release media of changing ionic strength, as discussed above. Therefore, one of ordinary skill in the art would be motivated to provide pramipexole according to Pospisilik '240 as a once daily controlled release preparation comprising a hydrophilic polymer and pregelatinized starch according to Vandecruys et al. with a reasonable expectation that the formulations provide a once daily formulation that exhibit the functional limitations as instantly claimed.

2. Claims 1, 3-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pospisilik '119 (US 2004/0068119) in view of Vandecruys et al. (WO 00/59477).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Pospisilik '119 teaches controlled release pellet or tablet compositions may be produced using pramipexole comprising a mixture of pramipexole salt, a suitable filler, such as microcrystalline cellulose, and a suitable release controlling agent comprising water and/or a water-insoluble macromolecular substance such as an acrylate polymer or a modified cellulose ([0061]). Pospisilik '119 further teaches that pramipexole is commercially available as the dihydrochloride salt ([0004]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Pospisilik '119 does not teach the controlled release pramipexole to have an *in vitro* release profile wherein at 2 hours no more than 20% pramipexole has dissolved, or

an *in vivo* absorption profile wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours, as instantly claimed. Pospisilik '119 also does not teach the controlled release pramipexole wherein the pramipexole is in the form of a dosage unit that is given as a daily dose in one dosage unit administered at one time, as instantly claimed.

However, Vandecruys et al. teach controlled release compositions comprising an active ingredient (i.e., anti-Parkinsonian drugs), pregelatinized starch and a hydrophilic polymer, wherein the combination of pregelatinized starch and hydrophilic polymer affords controlled release that is safeguarded or maintained in release media of changing ionic strength, i.e. along the entire gastrointestinal tract both in fasted as well as in fed conditions (Abstract; pg. 4, ln. 32 to pg. 5, ln. 3; and pg. 8, ln. 9). Vandecruys et al. further teach an example wherein the controlled release composition resulted in 11.99% release of the active ingredient at 1 hr, 17.74% release at 2 hr, 25.8% release at 4 hr and 33.26% release at 6 hr (Table 5).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to prepare controlled release pramipexole dihydrochloride salt compositions, as taught by Pospisilik '119, wherein the controlled release compositions comprise pregelatinized starch and a hydrophilic polymer and are suitable for once daily administration, as reasonably taught by Vandecruys et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments are the same as above. Therefore, the examiners response above is incorporated herein by reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1, 3-10, 12-21 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-23 of copending Application No. 10/626,166. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a pharmaceutical composition comprising pramipexole and a pharmaceutically acceptable excipient. Accordingly, the scope of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a), as discussed above.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616